

Vaccine Identification Standards Initiative (VISI)
Minutes of Conference Call
2000 September 13
11:00 am - 1:00 pm EDT

CALL PARTICIPANTS

Bruce G. Weniger (moderator)	National Immunization Program/CDC
Bill Purvis	Center for Biologics Evaluation and Research/FDA
Karen Chaitkin	Center for Biologics Evaluation and Research/FDA
Loretta Robertson	Center for Biologics Evaluation and Research/FDA
Yvonne McHugh	Chiron Corporation
Wikke Walop	Health Canada
Ron Filipski	Aventis Pasteur
James Mundt	Merck Vaccine Division
John Roberts	Uniform Code Council
Joanne Kim	American Academy of Pediatrics

SUMMARY

Introductions

Dr. Bruce Weniger welcomed all VISI participants, who identified themselves and their institutions in turn.

Printing Technology Subcommittee

Mr. John Roberts discussed the progress of the printing technology subcommittee after its July 27th meeting in Lawrenceville, New Jersey, to address the challenge of high-speed online printing of Reduced Space Symbology (RSS)/Composite barcodes, as VISI will specify on peel-off stickers for vaccine vials and syringes.

He announced that Merck and Aventis Pasteur are still interested in pilot testing for on-line RSS barcoded labels, however Chiron will be unable to participate. He is still awaiting responses from SmithKline Beecham (whose VISI liaison has changed from Gina Butler-Galliera) and from Wyeth-Lederle, but would be speaking with the latter company tomorrow. (Jack Barry [labelling

and specifications] and Michael Esposito [espositm@labs.wyeth.com, project administration/packaging services] are the Wyeth contacts on this subject.)

Aventis Pasteur will begin pilot testing in October and Merck will start in November. Pilot-testing will involve printing at least 1000 actual labels and conducting barcode scans to verify the printing quality. He would like also for the peel-off stickers to be tested in an actual vaccination clinic for scannability with existing barcode readers. It was suggested that a health maintenance organization, such as Kaiser, which may have scanners capable of reading RSS barcodes be recruited to conduct such real-world practice runs.

Possible NDC changes

Mr. Roberts stated that the Health Industry Standards Board (HISB) and FDA are considering changes to the global trade identification number for U.S. pharmaceuticals, which would potentially affect the current 10-digit NDC numbering system. HISB will meet on October 7th, with representation including the FDA.

At the “Promoting and Standardizing Bar Coding on Medication Packaging: Reducing Error and Improving Patient Care” meeting held in Chicago on 7-August-2000, there was some discussion of changing the length of the NDC number, as well as mandating that the NDC number be present on all pharmaceutical products. Jerry Phillips, from the FDA, proposed that the current NDC number be changed from a 10 digit number to 11 digits. However, the current UPC code can only accommodate 10 digits, without major changes to the global trade numbering conventions.

If any such changes are made, UCC would propose revising the 10-digit format to two substrings of 5 digits each. The first 5 for the manufacturer, and the second 5 for specific individual products, thus avoiding the confusion over different lengths allowed for the three current NDC substrings (“labeler” - 4 or 5 digits, “product” - 3 or 4, “package” - 1 or 2). A “proposed rulemaking” process would be required for such a major change.

Status of additional support for VISI

Dr. Weniger informed the group that funds have been secured to engage an editor to oversee improving the text and organization of the VISI application guidelines content, and various textual prototypes, such as the Uniform Vaccine Administration Record (UVAR) form. The editor would also help plan, coordinate, and announce the public comment phase, and tabulate and organize the feedback.

Funds were also secured to contract with webmaster who will be working on reorganizing the design, organization, and functioning of the website containing the VISI materials. This will include a new logo and layout, and fine tuning the NDC database to improve the search results screen.

Discussion of specific VISI components

1. RSS barcode mockups for vial stickers

Dr. Weniger said that the existing RSS mockups of barcodes superimposed on current actual vaccine labels still require revisions. These may include illustrating that the barcode and human readable NDC, lot number, and expiration date should be repeated on a portion of the label that remains on the vial. New mockups might also illustrate multiple peel-off stickers partially superimposed on the label, exposing only their online-printed data.

2. Online barcoding of vaccine cartons

Dr. Weniger also reported that the mockups for online printing on vaccine cartons would also need revisions to reflect the latest guidelines to use the UCC-EAN 128 symbol, rather than the UPC, and also to illustrate two options at each manufacturer's discretion: two separate barcodes (one preprinted with the NDC and one online-printed with the lot and expiration data) versus one online-printed barcode embedding all three numbers.

3. NDC database

Dr. Weniger said that Bindi Patel had modified the NDC database by adding URL web addresses linking to the actual vaccine product insert, if available, at the manufacturer's website. He commented that not all manufacturers yet provide their product inserts "online" at their website, but that it was a great feature and would be a welcome service for the immunization community.

4. *Vaccine Facts* information sidebar prototypes

As indicated on previous calls and in the VISI website, the CDC VISI coordinators plan to develop a new lexicon of standardized language for the *Vaccine Facts* sidebars, and to revise the existing mockups at the website (which were based on current language on vaccine cartons) to apply the standardized language to sidebars illustrating sample products from all manufacturers.

5. Vaccine and manufacturer abbreviations

Dr. Weniger mentioned the addition of abbreviations for esoteric and investigational future vaccines newly added to the VISI abbreviations list, including **AFT**, **ALZ**, **AME**, **AMT**, and **ANC** vaccines).

Dr. Wikke Walop opposed the use of subscripts in vaccine specifiers because they were hard to read and to write and can cause spacing problems. She also spoke against using the manufacturer's abbreviation within the specifier for a vaccine as a[n optional] method to specify indicate manufacturer. Dr. Weniger explained how subscripting was addressed and legibility problems solved in the universally-accepted and long-term use of abbreviations in chemical

notation, in which both general and scientific publications such as MMWR increase the font size and/or raise the level of the subscript for improved legibility, as in H_2O , H_2SO_4 , and $\text{C}_6\text{H}_{12}\text{O}_6$. (In the prior sentence, the standard font size of 12 point was increased to 16 point for the numbers in the molecular abbreviations prior to subscripting them.)

Dr. Weniger explained the recent decision faced by CDC for which abbreviations MMWR would use in the new pneumococcal conjugate vaccine statement from ACIP. The choices were either the ones promulgated by VISI ($\text{PNU}_{\text{cn-7}}$ and $\text{PNU}_{\text{ps-23}}$), by the American Academy of Pediatrics in its separate recommendations (PCV7 and 23PS), or by the ACIP working group on the statement (PCV7 and PPV23). Ultimately, CDC decided to use these last two abbreviations from its working group on this vaccine, without prejudice to future consideration and potential changes in the abbreviation nomenclature it may use.

Other/New Business

Dr. Wikke Walop announced that Health Canada will convene a meeting soon in Canada with vaccine manufacturers to discuss barcoding on vaccine packaging, and that she will report back to VISI on what transpires.

Next Steps

- ◆ Another conference call was set for Wednesday, November 21, at 11:00 am North American Eastern Standard Time. The following call information will be repeated and distributed via email closer to the event:

Call name:	VISI
Date:	Wednesday, 21 November
Time:	11:00 - 1:00 am EST (8:00-10:00 am PST)
Phone no.:	[+1] 404-639-3277
Toll-free in US:	1-800-311-3437
Access Code:	##### [Deleted from website-posted document. Contact Bindi Patel for access no.]

Minutes corrections and general contact for VISI

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